

Remarks

Claims 1 through 76 have been canceled without prejudice or disclaimer and with the understanding that Applicants may pursue the canceled subject matter in a continuation application. New claims 77 through 128 have been added. Exemplary support in Applicants' specification for each of the new claims is listed in the following table. No new matter has been introduced by any of the new claims. After entry of this amendment, claims 77 through 128 will be pending.

Claim Number	Exemplary Support in the Specification
77	original claim 1; page 4, lines 22-27; page 7, lines 9-10
78, 79, 82	page 7, lines 15-16
80, 81, 82	page 7, lines 16-18
83, 87, 99	original claim 51; page 17, lines 21-23
84, 88, 100	original claim 18; page 22, lines 15-16
85, 90, 101	original claim 20; page 22, lines 20-22
86	original claim 1; page 4, lines 22-27; page 7, line 11
91, 92, 93, 94	original claim 65; page 9, lines 1-16
95, 96	page 13, lines 1-18
97	page 9, lines 17-21
98	page 13, line 15
102, 103, 104	page 37, lines 25-26
105, 106, 107	page 10, lines 4-17
108, 109, 110, 111, 112, 113	page 15, lines 20-21; page 10, line 18 through page 11, line 27
114	page 21, lines 4-10
115, 116, 117, 118	page 16, lines 12-22; page 11, line 28 through page 12, line 2
119, 120, 121, 122, 123	page 18, lines 10-11; page 16, lines 12-17
124, 125, 126, 127, 128	page 20, lines 3-6

1. **Claim Objections**

The Examiner objects to claims 22-73 because of a numbering error. Claims 1 through 76 have been canceled, thereby mooting this objection.

2. Rejections under 35 U.S.C. 103(a)

A. Hackett in view of Hanna

Claims 1-29, 31-34, 38-39, 41-50, 52, 56-66 and 68-72 are rejected as being obvious over WO 91/16060 to Hackett *et al.* (“Hackett”) in view of Free Radic. Res. Commun. 14(4): 263-270 (1991) to Salim-Hanna *et al.* (“Hanna”). The Examiner asserts that Hackett discloses a method and a composition for inactivating biological fluids that includes the addition of amino acid stabilizers (citing page 4, lines 3-4; page 5, lines 15-17; page 7, lines 10-11; and page 17, lines 5-7). The Examiner acknowledges that Hackett fails to disclose a dipeptide stabilizer but relies upon Hanna for the teaching that the dipeptide carnosine protects biological materials during irradiation.

Without acquiescing to the merits of the rejection, claims 1-76 have been canceled. New independent claims 77, 86 and 97 require the presence of at least one dipeptide stabilizer. Contrary to the Examiner’s assertion, nothing in Hackett teaches or suggests the use of dipeptides as stabilizers. The passages cited by the Examiner in support of this statement are directed to sensitizers which are separate and distinct from stabilizers. The term “sensitizer” is a term of art that refers to a substance that selectively targets bacterial or viral contaminants in a biological material, rendering them more sensitive to inactivation by radiation. In contrast, the term “stabilizer” is a term of art that refers to a substance that reduces the damage that a biological material suffers during radiation. A sensitizer therefore increases the susceptibility of a substance to irradiation while a stabilizer decreases the susceptibility of a biological material to irradiation.

Hackett also differs from Applicants’ claimed invention in that Hackett requires the use of a sensitizer in its described irradiation process. In contrast, Applicants’ claimed methods of irradiation do not require the use of a sensitizer. The presence of sensitizers is not necessary for the operability of Applicants’ claimed methods of reducing the level of active biological contaminants or pathogens in tissue, a protein sample or serum. For at least the reasons discussed above, Hackett does not teach or suggest Applicants’ claimed invention. Hanna is limited to a discussion of the free radical scavenging activity of carnosine. A person of skill in this particular art would not be motivated to combine the teachings of Hackett, which describes peptides only as possible sensitizers, with Hanna, which addresses the oxidative-protective properties of carnosine. In the alternative, even if Hanna were combined with Hackett, Hanna cannot remedy the deficiencies present in Hanna that would render Applicants’ claimed invention obvious because there is no discussion of stabilizers in the primary reference. Applicants therefore request that the Examiner withdraw his rejection of the claims in view of the cited references.

B. Hackett in view of Hanna and further in view of Wiesealm

Claims 35-37 are rejected as being obvious over Hackett in view of Hanna and further in view of U.S. Patent 4,727,027 to Wiesealm *et al.* (“Wiesealm”). The Examiner acknowledges that Hackett and Hanna fail to teach the addition of a combination stabilizer to the biological material and relies on Wiesealm for allegedly providing this information.

Claims 35-37 have been canceled without acquiescing to the merits of the rejection, therefore the rejection is moot. For at least the reasons discussed above, the combination of Hackett with Hanna fails to render Applicants’ claimed invention obvious. Wiesealm cannot remedy the deficiencies present in the Hackett-Hanna combination. Applicants therefore request that this rejection be withdrawn.

C. Hackett in view of Hanna and further in view of Stogniew

Claim 40 is rejected as being obvious over Hackett in view of Hanna and further in view of U.S. Patent 6,258,821 to Stogniew *et al.* (“Stogniew”). The Examiner acknowledges that Hackett and Hanna fail to teach the addition of mixtures of two or more of the recited additional stabilizers in claim 40 and relies on Stogniew for allegedly teaching that propyl gallate and ascorbic acid stabilizers can be added to compositions.

Claim 40 has been canceled without acquiescing to the merits of the rejection, therefore the rejection is moot. For at least the reasons discussed above, the combination of Hackett with Hanna fails to render Applicants’ claimed invention obvious. Stogniew cannot remedy the deficiencies present in the Hackett-Hanna combination. Applicants therefore request that this rejection be withdrawn.

D. Hackett in view of Hanna and further in view of Purdum

Claims 30, 53-55 and 67 are rejected as being obvious over Hackett in view of Hanna and further in view of U.S. Patent 6,808,638 to Purdum (“Purdum”). The Examiner acknowledges that Hackett and Hanna fail to teach a prion as a pathogen, irradiation below ambient temperature, irradiation below the freezing point of the biological material, irradiation below the eutectic point of the biological material and the biological material in a glassy or vitrified state. However, the Examiner relies on Purdum for allegedly teaching each of these issues.

Claims 30, 53-55 and 67 have been canceled without acquiescing to the merits of the rejection, therefore the rejection is moot. For at least the reasons discussed above, the combination of Hackett with

Hanna fails to render Applicants' claimed invention obvious. Purdum cannot remedy the deficiencies present in the Hackett-Hanna combination. Applicants therefore request that this rejection be withdrawn.

E. Hackett in view of Hanna and further in view of Platz

Claim 51 is rejected as being obvious over Hackett in view of Hanna and further in view of U.S. Patent 6,828,323 to Platz *et al.* ("Platz"). The Examiner acknowledges that Hackett and Hanna fail to teach the concept of combining wavelengths of visible and UV light and relies on Platz for allegedly teaching the combination of visible and UV sources as one source emitting wavelengths covering both the visible light range and the UV light range.

Claim 51 has been canceled without acquiescing to the merits of the rejection, therefore the rejection is moot. Applicants submit that none of the substitute claims encompass subject matter similar to original claim 51.

F. Hackett in view of Hanna and further in view of Fike

Claims 73-76 are rejected as being obvious over Hackett in view of Hanna and further in view of U.S. Patent 6,383,810 to Fike *et al.* ("Fike"). The Examiner acknowledges that Hackett and Hanna fail to teach concentration ranges above 10% for the biological material present in a composition and relies on Fike for allegedly providing this information.

Claims 73-76 have been canceled without acquiescing to the merits of the rejection, therefore the rejection is moot. Applicants submit that none of the substitute claims encompass subject matter similar to original claims 73 to 76.

3. Conclusion

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, all claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested. Should the Examiner feel that there are any issues outstanding after consideration of this amendment, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37

C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

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